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| EXAMINER |
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SELLMAN, CACHET I

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| ART UNIT | PAPER NUMBER |
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1762

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09/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/654,562

Applicant(s)

SHMULEWITZ, ASCHER

Examiner

Cachet I. Sellman

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10, 13-15, 18, 21, 30 and 37-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3, 6, 8, 9, 27-29 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/2/2003, 9/9/2004, 3/7/2005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 6, 8, 27-29 and 31-36 are, drawn to a method for coating a stent, classified in class 427, subclass 2.24.
 - II. Claims 9-10, 13, 26, 30 and 37-42, drawn to a coating decision support system, classified in class 118, subclass 668.
 - III. Claims 14-15, 18 and 21, drawn to a method of using a coating decision support system, classified in class 118, subclass 416.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used in a different method such as one that does not require information be analyzed electronically.

3. Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used in a process where the treatment

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plan is not communicated to a person such as a physician rather it is implemented directly.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Paul Sorkin on 9/11/2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6, 6, 8, 27-29 and 31-36. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-10, 13-15, 18, 21, 26, 20 and 37-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is directed toward a system but claim 1 from which it depends is directed to a method. It is the Examiner's position that claim 8 is directed to the method of claim 1 in order to further examine the claim with respect to the prior art.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 8, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Castro et al. (US 6395326).

Castro et al. discloses a process for coating a prosthesis, such as a stent. The process comprise the use of a video camera to capture an image (providing data form a source); the image data is fed back to the motion control system (electronically analyzing the information to generate a coating plan); and using image information to control/direct the coating dispenser (col. 5, lines 1-9) as required by **claim 1**. The information received includes coating information (i.e. deometrical pattern of the coating) as required by **claim 8**.

As shown above, Castro et al. meets the limitations of **claim 27** by teaching receiving information regarding the stent to be coated (i.e. pattern of stent); analyzing the received information and using it to establish a coating profile and a function of the

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image received. The coating device is controlled using the coating profile as required by **claim 29**.

10. Claim s 1-2, and 27-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Shekalim et al. (US 6645547).

Shekalim et al. teaches a process for providing a coating to a stent just prior to implantation. The process supplies the coating using drop on demand ink jet printing that is associated with an optical scanning device (abstract). The output from the scanning device is used by the processing unit to determine the surface area aligned with the coating applicator is that which is to be coated and then controls the coating applicator to dispense the coating composition as required by **claim 1**. As stated the stent is coated at the time of surgery as required by **claim 2**. The information received is stent data as required by **claims 27 and 28**.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 2, 3, 6, 28, and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. as applied to claims 1 and 27 above in view of Admitted Prior Art, Shekalim et al. (US 6645547) and Bradbury et al. (US 2002/0007294).

The teachings of Castro et al. are as stated above. Castro et al. further teaches that stents can be implanted into a lumen to maintain vascular patency when performing percutaneous transluminal coronary angioplasty (PTCA). Damaged vasculature tissue can be treated by administering therapeutic substances to the treatment site such as anticoagulants, antiplatelets, and cytostatic agents. Local delivery of such substances are performed smaller total levels of medication is administered at a specific site which results in fewer side effects and achieves more effective results (col. 1, lines 12-60).

Castro et al. fails to teach that the stent is coated at the time of surgery as required by **claim 2**.

Shekalim et al. discloses the importance of coating the stents just prior to surgery rather than at the time of manufacturing the stent due to short shelf life of some drugs combined with the time span between manufacturing and implantation and the possible changes to the specific drug and dosage based on the patient at the time of surgery (col. 1, lines 25-40).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process of Castro et al. to include the coating device of Shekalim et al. to provide a coating to the stent just prior to implantation with accurate and up to date patient information so the dosage and drug used on the stent is appropriate for the patient's needs.

Castro et al. fails to teach that the information received is based on rules as required by **claim 6**. However, Bradbury et al. teaches a process for designing biomedical devices such as implantable devices which have gradual drug release. Bradbury et al. uses patient specific diagnostic data, converts that data into a digital computer file; converts the file to a model and then into machine instructions for forming the device (abstract and 0079). Bradbury teaches that this process significantly increases cost effectiveness and responsiveness and can further use a website to perform follow up tasks (abstract).

The information received is based on patient specific requirements such as patient records, lab data, or coating information (dosage of drug).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process of Castro et al. to include the process of using patient information to coat stents. One would have been motivated to do so because Bradbury et al. discloses how cost effective and responsive using actual patient information is rather than forming multiple coating stents and choosing and

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tweeking pre-made stents to have the proper dosage of substance on the stents depending on patient lab data etc.

It is well known in the art to coat stents using contact printing or injection printing as stated in the Admitted Prior Art (see paragraph 0031 of specification dated 9/2/2003).

The information is based on patient labs and records as required by **claims 8 and 29**.

The combination of Castro et al., Bradbury et al., and Shekalim et al., teach providing a coating to a stent which includes a therapeutic substance and is placed in a lumen of a patient (Castro et al.). The coating applied is dependent on the pattern on the stent to insure the stent is properly coated and no excess coating is applied. The coating method is also based on the condition of the lumen just prior to implantation, patient data/ labs, and the stent data (i.e. pattern) and electronically analyzing this information to form a coating profile (i.e drugs, dosage, and pattern of coating to the stent) as required by **claims 31 and 32**. Castro et al., Bradbury et al, and Shekalim et al. does not specifically teach the tailored dosage as described in **claims 33 and 35**. However, it is well known in the art that the dosage and drug is dependent on the patient's condition at the time of surgery as taught by Shekalim and Castro et al. teaches depositing the coating with varying thickness (col. 16, lines 45-47 and col. 21, lines 1-16). It would have been obvious to one having ordinary skill that by inputting the patients and the lumens condition into the computer that the resulting coating profile will provide the proper dosage based on the condition of the lumen.

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Castro et al. teaches that more than one composition can be applied to the stent concurrently or subsequently and that the second composition may differ for the first by the particular therapeutic substance that is used. It would have been obvious to one having ordinary skill in the art to use the two agents of claim 35 depending on the treatment that is needed for the patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cachet I. Sellman whose telephone number is 571-272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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cis

/William Phillip Fletcher III/
Primary Examiner